**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| **MYLAN PHARMACEUTICALS, INC.,** | : | |
| **Plaintiff,** | : | |
| | : | |
| **v.** | : | **Civ. No. 12-3824** |
| | : | |
| **WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,** | : | |
| **Defendants.** | : | |

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# M E M O R A N D U M

**Diamond, J.** **April 16, 2015**

Generic drug manufacturers, drug wholesalers, and retail pharmacies allege that Defendants Warner Chilcott and Mayne Pharmaceuticals have illegally thwarted competition in the sale of generic drugs. Defendants produce and sell Doryx, the branded version of delayed-release doxycycline hyclate, a prescription antibiotic used primarily to treat severe acne. Plaintiffs allege that Defendants conspired to protect their monopoly by "product hopping": making changes to the drug that ostensibly provided no significant improvements, but prevented pharmacists from automatically filling Doryx prescriptions with generic equivalents. Direct purchaser Plaintiffs, indirect purchaser Plaintiffs, and retailer Plaintiffs have all concluded modest settlements with Defendants, leaving generic drug maker Mylan Pharmaceuticals as the sole remaining Plaintiff. The Parties have filed cross motions for summary judgment. I will grant Defendants' Motions for Summary Judgment, deny Plaintiff's Motion, and enter judgment in favor of Defendants on all counts.

## THE PARTIES

Plaintiff Mylan Pharmaceuticals is the third-largest generic pharmaceutical company in the world. (Doc. No. 84 at 1.) Mylan has a "global portfolio of approximately 1,100 different

products." (Id.) In 2011, Mylan reported $6.13 billion in revenue and estimated that one of every eleven prescriptions dispensed in the United States was for a Mylan product. (Id. at 3.) Defendant Mayne Pharmaceuticals is an Australian-based pharmaceutical company that has six products, including Doryx. Mayne reported $50.1 million in sales in 2011. (Id. at 4.) Defendant Warner Chilcott is a United States-based pharmaceutical company that distributes and promotes Doryx domestically pursuant to a License Agreement with Mayne. Warner Chilcott reported $2.7 billion in revenue in 2011, 93% of which came from eight products. (Id. at 4.)

## BACKGROUND

Several oral tetracyclines are used to treat acne: doxycycline monohydrate, doxycycline hyclate, and minocycline. (W.C. Mot. S.J. at 22-23.) Doryx is the branded form of delayed-release doxycycline hyclate. (Id.) To decide the Motions before me, I must consider the product history of Doryx—branded and generic. In doing so, I have set out those record facts that are undisputed and construed them in the light most favorable to Mylan. I have disregarded Mylan's allegations that are without evidentiary support. See Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Jones v. UPS, 214 F.3d 402, 407 (3d Cir. 2000) ("unsupported allegations" cannot defeat summary judgment). I have accepted as true Mylan's remaining factual allegations and have construed them in the light most favorable to Mylan.

### I. Regulatory Procedures

The Food, Drug and Cosmetic Act requires Food and Drug Administration approval before any drug may be marketed. 21 U.S.C. § 301 et seq. The manufacturer must submit to the FDA a "New Drug Application" and prove the drug's safety and efficacy through extensive clinical trials. The FDCA originally obligated an applicant seeking to market a new generic drug to meet the same requirements as one seeking FDA approval of a branded drug, including full

clinical trials. With the 1984 adoption of the Hatch-Waxman Act, however, generic manufacturers could submit an "Abbreviated New Drug Application" to expedite the approval process and lower costs. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. An "ANDA" filer must show only that its drug is bioequivalent to an already approved "reference" drug. Jessie Chang, Note, An Antitrust Analysis of Product Hopping in the Pharmaceuticals Industry, 108 Colum. L. Rev. 1471, 1479 (2008).

If the generic drug is the branded drug's bioequivalent and the two are the same dosage, strength, and form, the FDA identifies the generic as the branded version's "AB-rated" equivalent. 21 U.S.C. § 355. Most states have incorporated this AB-rating into their own statutes. Under these "Drug Product Selection" laws, a pharmacist who fills a prescription for a branded drug can—or, in some states, must—substitute an AB-rated generic version (which is usually less expensive than the branded version), unless the prescribing physician notes "dispense as written." Chang, Product Hopping, at 1479. Twelve states require pharmacists to substitute generic drugs, unless the physician prescribes otherwise. Thirty-nine states permit substitution in such circumstances. (W.C. Resp. to Mylan S.J. at 30.)

## II. Doryx Development

Immediate-release doxycycline hyclate has been available to treat acne since the 1960s, when Pfizer launched Vibramycin. (W.C. Resp. to Mylan S.J. at 5.) Doryx capsules—delayed-released doxycycline hyclate—were first approved by the FDA in 1985 and launched by Mayne that same year. The capsules were not patent-protected. (Id.) They included enteric-coated pellets which would allow delayed release, intended to reduce the nausea and stomach irritation caused by immediate-release doxycycline. (Mayne S.J. at 5.) Mayne also produced an

authorized generic version of Doryx. (W.C. Resp. to Mylan S.J. at 6.) Warner Chilcott, then a subsidiary of Warner Lambert, distributed branded and generic Doryx for Mayne in the United States. (Id.)

Sales of branded and generic Doryx capsules were sluggish in the early 1990s. (Id.) In 1994, Mayne (then known as F.H. Faulding & Co.), and Warner Chilcott entered into an exclusive license agreement intended to increase Doryx sales: (1) Mayne agreed to take its generic Doryx off the market and act as the exclusive manufacturer and supplier to Warner Chilcott of branded Doryx; (2) Warner Chilcott agreed to distribute branded Doryx in the United States and to market Doryx through targeted promotions to dermatologists in exchange for the rights to all income from the domestic sales of the drug. (W.C. Ex. 121.) Mayne agreed not to sell Doryx domestically, provided Warner met minimum Doryx purchase and sales thresholds. (Mayne S.J. at 9.) Although the License Agreement originally ran from 1997 to 2004, Mayne and Warner Chilcott have renewed the Agreement several times and it remains in force today. (Id. at 10.) The Agreement increased Doryx sales more than twenty-fold by 2005. (W.C. Resp. to Mylan S.J. at 33-34 & Table 2.)

## III. "Product Hopping"

The 1997 License Agreement obligated Defendants to enter into negotiations "with respect to a new agreement pursuant to which [Mayne] would develop a doxycycline hyclate delayed release tablet" for Warner Chilcott to distribute in the United States. (W.C. Ex. 121 at 6.) That tablet development took over six years, during which Mayne: (1) reformulated delayed-release doxycycline hyclate, and (2) added a stabilizing coat solution to improve the drug's shelf-life. (Mayne S.J. at 16; W.C. Exs. 226, 191.)

In May 2005, the FDA approved Defendants' NDA for Doryx 75 and 100 mg tablets. (W.C. Ex. 211.) The tablets were introduced in September 2005, and Defendants took steps to switch the market for Doryx capsules to Doryx tablets. (Mylan S.J. at 12.) They: (1) stopped selling the capsules to wholesalers (Mylan Ex. 59); (2) removed Doryx capsules from the Warner Chilcott website (Mylan Ex. 62); (3) worked with retailers to "auto-reference" the Doryx tablet whenever a doctor filed a Doryx prescription (Mylan Ex. 61); (4) informed wholesalers, retailers, and doctors that "Doryx Capsules have been replaced by Doryx Tablets" (Mylan Ex. 63); (5) destroyed some of their remaining capsule inventory (Mylan Ex. 73); and (6) bought back some portion of the remaining capsule inventory (Mylan Ex. 68, 69, 71).

Beginning in January 2007, Defendants worked to develop a 150 mg strength Doryx tablet with a single "score"—a groove running across the tablet's surface. The "score" allows the user to split a 150 mg Doryx tablet into two 75 mg doses. Defendants submitted a supplemental NDA for the 150 mg single-scored tablet in December 2007. (W.C. Ex. 358.) The FDA granted its approval in June 2008 and Defendants launched the 150 mg Doryx single-scored tablet a short time later. (W.C. Ex. 216.)

In January 2009, Defendants stopped promoting the 75 and 100 mg tablets, and began an "aggressive marketing program[]" for the 150 mg dose tablet. (Mylan Ex. 130.) By late March 2009, the 150 mg tablet represented 71% of all new Doryx prescriptions and 61% of total Doryx prescriptions. (Id.) In May 2010, Warner Chilcott reported to investors that the company was able to transfer about 90% of its Doryx franchise into the 150 mg tablet. (Mylan Ex. 132.)

While they developed the 150 mg tablet, Defendants also developed scored versions of their existing 75 and 100 mg Doryx tablets. Defendants submitted the supplemental NDAs for 75 and 100 mg single-scored Doryx tablets in June and August 2008, and received approval in

February and March 2009. (W.C. Exs. 360, 361, 248, 123.) Warner Chilcott stopped distributing the 75 and 100 mg single-scored Doryx tablets in March and August 2011, when the great majority of Doryx prescriptions were for the 150 mg tablet. (W.C. Exs. 362, 363.)

In March 2010, Defendants began developing a dual-scored 150 mg Doryx tablet, which could be broken into two or three pieces, thus providing dosing options of 50, 100, and 150 mg. (W.C. Ex. 251.) The firms submitted the supplemental NDA for the dual-scored 150 mg tablet in February 2011. (W.C. Ex. 223.) After receiving approval in September 2011, Warner Chilcott stopped distributing single-scored 150 mg tablets. (Id.; Mylan S.J. at 28.)

Finally, Defendants introduced an unscored 200 mg Doryx tablet in April 2013 as a once-a-day dosing regimen for chlamydia. (W.C. Resp. to Mylan S.J. at 17-18.) Today, Defendants produce and sell the 200 mg and 150 mg dual-scored Doryx tablets in the United States. (Id. at 18.)

## IV. Mylan's Development of Generic Doryx

Although Mylan first began developing a generic Doryx capsule in April 2003, by the time Doryx tablets launched in September 2005, Mylan still had no viable generic capsule. (W.C. Resp. to Mylan S.J. at 19-21.) Mylan did not abandon the capsule effort until January 2006, after the FDA had approved a generic Doryx capsule manufactured by Sandoz, which launched in July 2006. (Id.; W.C. Exs. 261, 382.)

By September 2006, Mylan had prepared the tablet formulation for a wholly-coated Doryx tablet to achieve delayed release. (Mylan S.J. at 27.) In March 2008, Mylan submitted an ANDA for its generic 75 and 100 mg Doryx tablets; the FDA granted its approval in December 2010. (Mylan Ex. 207.)

While Mylan's ANDA application was pending in March 2009, Mayne and Warner Chilcott added score lines to their 75 and 100 mg tablets. The Parties dispute whether this alone delayed the market entry of Mylan's generic. (Mylan S.J. at 27.) It appears that at least part of the delay resulted from the FDA's issuance to Mylan of several deficiency notices unrelated to the scoring issue. (W.C. Ex. 377 (timeline of Mylan tablet development); Mylan Ex. 209, 210, 110.) I will nonetheless resolve this dispute in Mylan's favor, and find that the decision to add score lines to branded 75 and 100 mg Doryx tablets delayed the entry of Mylan's generic until December 2010. (Mylan Ex. 213.)

At that time, while Mylan's were the only generic Doryx tablets on the market, the FDA—acting in accordance with federal law—granted Mylan 180 days exclusivity, preventing other generic drug manufacturers from introducing their own generic versions of Doryx. 21 U.S.C. § 355; (Mylan Ex. 213 (FDA approval of 75 and 100 mg generics).) When Defendants stopped selling 75 and 100 mg Doryx tablets in 2011, Mylan was the exclusive seller of 75 and 100 mg tablets—branded or generic—for two and a half years. (W.C. Opp. at 23.) During that period, Mylan raised the tablet prices to levels that were higher than Defendants' last reported prices for Doryx. (W.C. Resp. to Mylan S.J. at 23; W.C. Ex. 267.)

After Defendants' June 2008 launch of a 150 mg single-scored tablet, Mylan immediately began working on a generic version, and submitted an ANDA in December 2008. The FDA tentatively granted approval in June 2011. (Mylan Exs. 217-219.)

Finally, Defendants launched the dual-scored 150 mg tablet in September 2011 and petitioned the FDA, asking—as they had with the single-scored 150 mg tablet—that ANDA generic applicants match the dual scoring. (Mylan Ex. 222.) An e-mail from Mayne's CFO predicted that it was "likely that the FDA will make Mylan alter their generic to be a dual scored

product." (Mylan Ex. 146.) The FDA rejected the request, however, noting that it might approve an ANDA for a 150 mg generic Doryx with a single score. (Mylan Ex. 149.) The FDA determined in February 2012 that Mylan's single-scored 150 mg tablet would be AB-rated—at least initially—to Defendants' dual-scored 150 mg tablet. (Mylan Ex. 221.) Mylan thus launched its first 150 mg generic Doryx in February 2012. (Id.)

## V. The Challenged "Hops"

Mylan alleges that each of the following changes to Doryx was an anti-competitive product hop:

1. 2005 change from 75 and 100 mg capsules to 75 and 100 mg tablets;
2. 2008 introduction of a single-scored 150 mg tablet;
3. 2009 addition of a single score to 75 and 100 mg tablets; and,
4. 2011 change from single to dual score on the 150 mg tablet.

(Mylan S.J. at 11-21.)

Defendants insist that each of these product changes improved Doryx and benefited consumers. (W.C. Resp. to Mylan S.J. at 4.) Defendants offer evidence that they had legitimate business reasons for each product change, including: (1) shelf-life stability issues with Doryx capsules; (2) the increased risk of esophageal injuries with capsules; (3) concern from French and Swedish regulators over the risk of esophageal injury; (4) a putative class action in the United States alleging esophageal injury from capsules; and, (5) dosing flexibility. (Resp. to Mylan S.J. at 4-5, 7-13.)

Mylan counters that any purported "legitimate business justifications . . . collapse[] under close scrutiny." (Mylan S.J. at 2.) Mylan has presented evidence that the stability problems could have been solved without switching to tablets. (Id. at 24-25.) Moreover, despite pressure

from foreign regulators over the risk of esophageal injury, Doryx tablets were introduced only in the United States. (Id. at 22.) Doryx capsules continue to be sold in other jurisdictions and, as recently as 2011, Defendants considered re-introducing capsules into the United States. (Mylan Ex. 160, 172.) The products liability litigation to which Defendants refer was a putative class action that never got past the certification stage. (Mylan Reply at 10.)

Mylan has also presented evidence that Defendants' product changes were intended to delay generic market entry. Internal Mayne and Warner Chilcott documents provide that Doryx product changes were a "defen[s]e strategy to generic competition." (Mylan Ex. 31; see also Mylan Ex. 49 (tablet development is "an anti-generic strategy for Doryx"); Mylan Ex. 53 ("Th[e] tablet is to be utili[z]ed as an anti-generic strategy should competition to the existing capsule eventuate."); Mylan Ex. 107 (tablet scoring is an "additional product protection strategy"); Mylan Ex. 130 ("This dominance of Doryx by the 150 mg dose strength . . . provides some time for WC and [Mayne] to complete developments for new dose forms further discouraging generic competition.").)

That Defendants' product "hops" provided some benefit to consumers seems undeniable. For instance, the scoring of Doryx tablets made it easier to reduce the medicine's dosage. Nonetheless, at summary judgment, I am compelled to find that Defendants made the Doryx "hops"—even the six-year developmental "hop" from capsules to tablets—primarily to defeat generic competition. See In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 316 n.12 (3d Cir. 2010) (in an antitrust case, disputed factual questions about reasonableness may not be resolved at summary judgment but usually should be left to jury).

## PROCEDURAL HISTORY

Plaintiffs—then generic drug manufacturers and pharmaceutical wholesalers—filed the instant action on July 6, 2012. (Doc. No. 1, Compl.) The gravamen of their Complaint was that Defendants took improper advantage of the regulatory system by making "tactical modifications" to Doryx to thwart generic competition. (Mylan S.J. at 1.) In denying Defendants' Motions to Dismiss, I deferred until summary judgment addressing the question of whether product hopping is anticompetitive. (Doc. No. 280.)

On April 1, 2013, Direct Purchaser Plaintiffs and Indirect Purchaser Plaintiffs filed Motions for Class Certification, which Defendants opposed. (Doc. Nos. 151, 155, 228, 247.) While the Motions were pending, the Parties began settlement discussions. Direct Purchaser Plaintiffs reached a settlement on December 24, 2013. (Doc. No. 452.) I provisionally certified a settlement class on February 18, 2014 and, after a final fairness hearing, granted final certification on September 15, 2014. (Doc. No. 665.) The Retailer Plaintiffs filed a Stipulation of Dismissal on May 27, 2014. (Doc. No. 638.) Indirect Purchaser Plaintiffs reached a settlement on June 27, 2014, which I preliminarily approved on September 4, 2014 and, after a fairness hearing, I granted final certification on January 23, 2015. (Doc. No. 679.)

As sole remaining Plaintiff, Mylan alleges: (1) monopolization under Section 2 of the Sherman Act; (2) attempted monopolization under Section 2; (3) an agreement between Warner Chilcott and Mayne in restraint of trade under Section 1 of the Sherman Act; and (4) tortious interference under Pennsylvania state law. (Compl.) The Parties have filed cross motions for summary judgment.

## SUMMARY JUDGMENT STANDARDS

Upon motion of any party, summary judgment is warranted "if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party must show the absence of any genuine issue of material fact. Celotex, 477 U.S. at 323. An issue is material only if it could affect the result of the suit under governing law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). I "must view the facts in the light most favorable to the non-moving party," and make every reasonable inference in that party's favor. Hugh v. Butler Cnty. Family YMCA, 418 F.3d 265, 267 (3d Cir. 2005). If I then determine that the moving party is entitled to judgment as a matter of law, summary judgment is appropriate. Celotex, 477 U.S. at 322.

## DISCUSSION

### I. Section 2 Claim

It is unlawful to monopolize, attempt to monopolize, or conspire to monopolize interstate or international commerce. 15 U.S.C. § 2. The Sherman Act protects competition, not competitors. Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 338 (1990); Brunswick Corp. v. Pueblo Bowl O-Mat, Inc., 429 U.S. 477, 484, 488-89 (1977). Indeed, conduct that makes it more difficult for competitors to keep pace—even conduct that actively harms competitors—is not proscribed by the Sherman Act unless it harms competition itself. Eichorn v. AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001) ("[A]n individual plaintiff personally aggrieved by an alleged anti-competitive agreement has not suffered an antitrust injury unless the activity has a wider impact on the competitive market.").

*A. Monopolization Claim*

To establish monopolization, Mylan must prove: (1) possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power by means other than a superior product, business acumen, or historic accident. Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 306 (3d Cir. 2007). Here, Mylan can prove neither element.

*1. Monopoly Power*

A company has monopoly power if it can profitably raise prices without causing competing firms to expand output and drive down prices. Harrison Aire, Inc. v. Aerostar Int'l, Inc., 423 F.3d 374, 380 (3d Cir. 2005). Such power can be proven directly—through evidence of control over prices and the ability to exclude competition—or indirectly through evidence of a high market share. Broadcom Corp., 501 F.3d at 307 n.3. To survive a motion for summary judgment, Mylan must present "economically plausible evidence" supporting its claim that Defendants held monopoly power. Harrison Aire, Inc., 423 F.3d at 380.

Direct evidence of monopoly power is "only rarely available." Id. at 381. Nonetheless, "[t]he existence of monopoly power may be proven through direct evidence of supracompetitive prices and restricted output." Broadcom Corp., 501 F.3d at 307. "[T]o support a claim that defendants set supra-competitive prices, antitrust plaintiffs must provide an analysis of the defendant's costs, and show that the defendant had an 'abnormally high price-cost margin' and that they 'restricted output.'" Carpenter Tech. Corp. v. Allegheny Technologies Inc., No. 08-2907, 2011 WL 4528303, at *12 (E.D. Pa. Sept. 30, 2011) (quoting Geneva Pharms. Tech. Corp. v. Barr Labs, Inc., 386 F.3d 485, 500 (2d Cir. 2004)). "[W]ithout evidence that sheds light on material factors such as [the alleged monopolist's] price relative to its total costs (marginal and

fixed) and whether output was restricted, monopoly power cannot be found as a matter of law." In re Remeron Direct Purchaser Antitrust Litig., 367 F. Supp. 2d 675, 681 n.10 (D.N.J. 2005).

Mylan has not made a serious effort to present direct evidence of Defendants' monopoly power. To begin, Mylan offers no evidence of Defendants' "price-cost margins" for Doryx, nor does it explain whether those margins were abnormally high. (Mylan S.J. at 32.) Mylan's economic expert, Dr. Rubenfeld, elected to forego any analysis of Defendants' margins because, as he opined, other available evidence of monopoly power was "more compelling," and margins are "difficult to measure" and "imperfect indicators of market power." (Mylan Ex. 2, Rubenfeld Rep. at 34-35.) Dr. Rubenfeld nonetheless states that at least some of Defendants' data suggested a margin of 83% in the second quarter of 2006—without explaining whether that figure is abnormally high. (Id. at 35.) Regardless of whether or not evidence of Defendants' marginal and fixed costs was "compelling" or "difficult to measure," it is still required to prove monopoly power directly. Carpenter Tech. Corp., 2011 WL 4528303, at *12. Mylan has not made such a showing. Mylan also fails to show that Defendants restricted Doryx output to maintain monopoly profits, and fails to discuss the quantity of Doryx Defendants manufactured during the relevant period. (Mylan S.J. at 32.) In these circumstances, Mylan has not presented plausible direct evidence of market power.

Mylan thus must prove with indirect evidence that Defendants possessed monopoly power. Harrison Aire, Inc., 423 F.3d at 381. Mylan must first define the relevant market in which Defendants were alleged monopolists. Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 436 (3d Cir. 1997); see also Broadcom Corp., 501 F.3d at 307 ("The scope of the market is a question of fact as to which the plaintiff bears the burden of proof."). Mylan must

then produce evidence of Defendants' "dominant share of that market, and of high barriers to entry." Harrison Aire, Inc., 423 F.3d at 381.

The boundaries of the relevant product market are determined by a product's reasonable interchangeability of use between the product and its substitutes. Queen City Pizza, Inc., 124 F.3d at 436. "Interchangeability implies that one product is roughly equivalent to another for the use to which it is put; while there may be some degree of preference for the one over the other, either would work effectively." Id. (quoting Allen–Myland, Inc. v. Int'l Bus. Mach. Corp., 33 F.3d 194, 206 (3d Cir.1994)). Products in a relevant market are also characterized by cross-elasticity of demand; that is, whether "the rise in the price of a good within a relevant product market would tend to create a greater demand for other like goods in that market." Id. (quoting Tunis Bros. Co., Inc. v. Ford Motor Co., 952 F.2d 715, 722 (3d Cir. 1991)). Courts are reluctant to find single-product markets, noting that every manufacturer in a single-product market will have monopoly power. Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp., 959 F.2d 468, 480 (3d Cir. 1992) (en banc) ("Except in rare circumstances, courts reject market definitions consisting of one supplier's products where other brands compete."); Edward J. Sweeney & Sons, Inc. v. Texaco, Inc., 637 F.2d 105, 118 (3d Cir. 1980). A proposed market is legally insufficient if it "clearly does not encompass all interchangeable substitute products." Queen City Pizza, 124 F.3d at 436.

Mylan urges a single-product market: branded and generic Doryx. (Mylan S.J. at 34.) Within this "market," Defendants held 100% of sales until generic entry, and currently "hold over 60% of sales." (Id. at 36.) Mylan excludes from its proposed market all other oral tetracyclines prescribed for acne, including branded and generic forms of immediate-release doxycycline hyclate, doxycycline monohydrate, and minocycline hydrochloride. Defendants

counter that the relevant market necessarily includes these oral tetracyclines. (W.C. S.J. at 22.) Within this market, it appears that Defendants' market share never exceeded 18%. (Id. at 29.)

In seeking to prove the relevant market, Mylan relies almost entirely on two expert reports. One is authored by economist Phillip Nelson, who opines that acne treatment is "highly individualized" and that Doryx has "unique characteristics that differentiate it from other antibiotics," including a distinct gastrointestinal side-effect profile due to Doryx's delayed-release coating. (Mylan Ex. 19, Nelson Rep. at 18, 21, 26.) Dr. Nelson acknowledges, however, that these "other" drugs are "similarly effective" at treating acne. (Id. at 21.) The second report, prepared by dermatologist Mark Jackson, makes many of the same points. Dr. Jackson opines that effective acne treatment must be "tailored to the patient." (Mylan Ex. 239, Jackson Rep. at 13.) Dr. Jackson believes that Doryx is not "functionally interchangeable" with other tetracyclines given differences in "tolerability and side effects." (Id. at 24.) Mylan argues that its evidence, "at a minimum" establishes that Doryx is a "relevant antitrust submarket under Brown Shoe Co. v. United States, 370 U.S. 294 (1962)." (Mylan S.J. at 34.)

An expert report that has no record support cannot defeat summary judgment. Advo, Inc. v. Philadelphia Newspapers, Inc., 51 F.3d 1191, 1198 (3d Cir. 1995) (expert testimony without a factual foundation cannot defeat a motion for summary judgment); Rosefielde v. Falcon Jet Corp., 701 F. Supp. 1053, 1070 (D.N.J. 1988) ("[A]ntitrust plaintiff may not be allowed to defeat a motion for summary judgment with an expert report that lacks factual support in the record." (citing Pennsylvania Dental Ass'n v. Med. Serv. Ass'n of Pennsylvania, 745 F.2d 248, 262 (3d Cir. 1984))).

The record abounds with uncontradicted evidence—some of it Mylan's—confirming and reconfirming the interchangeability of Doryx with other oral tetracyclines. There is a consensus

among dermatologists that all oral tetracyclines treat acne with similar effectiveness and so are interchangeable for that purpose. (See, e.g., W.C. Ex. 38 at 10.) The FDA has approved virtually identical labeling for most of these drugs, stating that in cases of "severe acne" the drugs "may be useful adjunctive therapy." (W.C. App. 2 (collecting label information).)

Managed care organizations have sought to constrain patients to substitute Doryx with other, less costly tetracyclines to treat acne. Some organizations have removed Doryx as a reimbursable medication; others have limited any reimbursement. (W.C. S.J. at 26.) A number of managed care organizations sent notices to healthcare providers urging them to substitute other oral tetracyclines for Doryx. (Id. at 26-27.) The University of Pittsburgh Health Plan, for instance, characterized generic immediate-release doxycycline, tetracycline, and minocycline as "substitutes for Doryx," and actively encouraged physicians to switch from Doryx to these other drugs. (W.C. Ex. 64; see also W.C. Ex. 45 (Cigna); W.C. Ex. 39 (BCBS Florida); W.C. Ex. 21.).) Indeed, Mylan's own expert confirmed that Doryx is but one of a class of antibiotics used to treat acne. (See, e.g., Mylan Ex. 22 at 16 (noting other oral antibiotics used to treat acne).)

Years of internal marketing documents further confirm that tetracyclines are reasonable substitutes for one another. Defendants consistently defined the market in which Doryx competed as including other tetracyclines. In 1997, when Defendants began planning the branded strategy for Doryx and the development of Doryx tablets, they noted that capturing 20% of the then 800,000 prescriptions for Vibramycin (the branded version of immediate-release doxycycline) would result in "over $13 million in annualized Doryx sales." (W.C. Ex. 131.) The Doryx 2008 Brand Plan noted that Doryx had a 12% market share among its competitors—Adoxa, Dynacin, Solodyn, Oracea, generic minocycline, and generic doxycycline. (W.C. Ex. 92.) Defendants' competitors defined the market in the same fashion. (See, e.g., W.C. Ex. 70

(internal Foguera documents describing Adoxa as competing with Doryx and other tetracyclines); W.C. Ex. 72 (internal Aqua documents describing Monodox as competing with Doryx and other tetracyclines); W.C. Ex. 83 (internal Medicis documents describing Solodyn/Dyancin as competiting with Doryx and other tetracyclines).) Finally, Mylan itself repeatedly listed different tetracyclines in the "Same/Similar" product category in internal product analyses. (W.C. App. 4H, 4I & 4J.)

Advertising also confirms that oral tetracyclines are effective substitutes for each other. In an advertisement titled "Facts Don't Lie," Adoxa stated that there "is no clinical data to support the efficacy of Doryx over any other doxycycline product." (W.C. Ex. 69.) When Adoxa introduced a single-scored 150 mg tablet before Doryx, it boasted that Adoxa was the "1st and only doxycycline scored tablet." (W.C. Ex. 87; see also W.C. Ex. 71 (Oracea ads attacking Doryx); W.C. Ex. 72 (Mondox ad campaign attacking Doryx).) In response, Defendants emphasized that Doryx is superior to other oral tetracyclines. A 2006 Doryx ad, for example, touted the advantages of Doryx over Oracea, including dosing flexibility, safety, and value. (W.C. Ex. 60.)

Finally, Defendants produced evidence of cross-elasticity of demand between Doryx and other oral tetracyclines. (W.C. Ex. 53, Addanki Rep. at 41-46.) From July 2005 to February 2008, Defendants offered a "fixed-amount coupon" for Doryx to help patients offset their co-pays. (Id. at 41.) In February 2009, Defendants discontinued the fixed-amount coupon and began offering "pay no more" cards, which paid all but $25 of a patient's Doryx costs. (Id.) Defendants switched back to a less generous fixed-amount coupon in 2011, after concluding that the pay no more cards were too expensive. (Id. at 42) In response, doctors, pharmacists, and patients switched from Doryx to other oral tetracyclines. These decreased sales caused

Defendants to reverse course; in August 2011, they went back to the pay no more cards. (Id. at 42.) A regression analysis of these events confirms the cross-elasticity of demand: when Defendants increased the price of Doryx, its sales decreased and the sales of other oral tetracyclines increased. There was "a statistically significant decline in the new prescriptions for Doryx during the first seven months of 2011 when the fixed subsidy coupon program structure was in effect," and a "statistically significant increase in the new prescriptions for Adoxa, generic immediate-release doxycycline hyclate, and generic immediate-release doxycycline monohydrate, as well as generic delayed-release doxycycline hyclate." (Id. at 44.) Mylan argues that this evidence is insufficient because there was "no clear pattern of substitution," ignoring that Mylan itself carries the burden of defining the relevant market. (Mylan Resp. to W.C. S.J. at 23.) Mylan cannot dispute, however, that an increase in Doryx's price in 2011 caused a statistically significant increase in the sales of at least some oral tetracyclines that ostensibly could not serve as Doryx substitutes.

Mylan argues that Doryx is not reasonably interchangeable with other oral tetracyclines because doctors have unique preferences in prescribing antibiotics to treat acne, and Doryx has a unique side effect profile that differentiates it from other oral tetracyclines. (Mylan S.J. at 34-36.) These subtle differences, however, do not mean that other oral tetracyclines are not a reasonable substitute for Doryx. Interchangeability is defined by rough equivalence, not perfect correspondence. Queen City Pizza, Inc., 124 F.3d at 436; see also Town Sound & Custom Tops, Inc., 959 F.2d at 480 ("[U]niqueness confers economic power only when other competitors are in some way prevented from offering the distinctive product themselves."). Moreover, even if there are patients for whom Doryx is a preferred treatment, the "test for a relevant market is not commodities reasonably interchangeable by a particular plaintiff, but 'commodities reasonably

interchangeable by consumers for the same purposes.'" Queen City Pizza, Inc., 124 F.3d at 438 (quoting United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 395 (1956)).

The record thus makes plain that the market in which Doryx competes includes other oral tetracyclines. No reasonable juror could find otherwise. Harrison Aire, Inc., 423 F.3d at 380. Defendants' share of this market—some 18%—is not predominant. United States v. Dentsply Int'l, Inc., 399 F.3d 181, 187 (3d Cir. 2005) ("Absent other pertinent factors, a share significantly larger than 55% has been required to established prima facie market power.").

In the absence of a predominant market share, I may consider other factors that might establish that Defendants held monopoly power: the size and strength of competing firms, freedom of entry, pricing trends and practices in the industry, the ability of consumers to substitute comparable goods, and consumer demand. Id. at 187. These factors weigh against finding that Defendants have monopoly power. As I have discussed, Mylan—Defendants' competitor in this market—is more than twice the size of Warner Chilcott, and 100 times the size of Mayne. (Doc. No. 84 at 1.) There is also freedom of entry into the oral tetracycline market. Since 2005—when Defendants purportedly were monopolists dominating the market—nearly forty oral tetracyclines gained FDA approval. (W.C. App. 5.) As I have described, the market for oral tetracyclines is quite competitive and consumers are able to substitute "comparable goods."

Finally, Mylan's argument that Doryx is an antitrust "submarket" within the market for oral tetracyclines also fails. Brown Shoe Co., 370 U.S. at 325. A submarket's boundaries are determined by "such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized

vendors." Id. I have already explained why Doryx's features, however "unique," still allow the substitution of other oral tetracyclines. Moreover, Mylan has presented no evidence that the industry or public identifies Doryx as a "separate economic entity." On the contrary, the undisputed evidence shows that the industry and public identify Doryx as just one product in the crowded, competitive market for oral tetracyclines. Mylan has also failed to produce evidence suggesting that Doryx has distinct customers, distinct prices, or specialized vendors. Again, the evidence shows just the opposite: Doryx is therapeutically equivalent to other oral tetracyclines.

In sum, Mylan has failed to produce economically plausible evidence to prove that Defendants hold monopoly power in the relevant market. Nor has Mylan shown that other factors might support finding that Defendants exercise monopoly power in the absence of predominant market share. In these circumstances, Mylan has not made out a Section 2 claim. Broadcom Corp., 501 F.3d at 307. Accordingly, I will enter summary judgment for Defendants on that claim. See Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 468-69 (1992) ("If the plaintiff's theory is economically senseless, no reasonable jury could find in its favor, and summary judgment should be granted."); Harrison Aire, Inc., 423 F.3d at 380.

*2. Anticompetitive Conduct*

Because Mylan's Section 2 claim fails in the absence of Defendants' monopoly power, in other circumstances I would not address whether Defendants engaged in anticompetitive conduct. See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) ("To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*."). Because Mylan's remaining claims require me to determine if Defendants' conduct was anticompetitive, however, I will do so now.

In sum, I conclude that Mylan has failed to produce initial evidence of anticompetitive conduct. I thus need not proceed with the burden-shifting framework and determine whether Defendants have proffered nonpretextual, procompetitive justifications for their product changes, whether Mylan has rebutted those justifications, or whether the product changes were, on balance, procompetitive or anticompetitive. United States v. Microsoft Corp., 253 F.3d 34, 58-59 (D.C. Cir. 2001).

"Anticompetitive conduct may take a variety of forms, but it is generally defined as conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits." Broadcom Corp., 501 F.3d at 308. "[I]t is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." Dentsply Int'l, Inc., 399 F.3d at 191. When an alleged monopolist introduces a new product, the question is whether it is "engaging in exclusionary conduct as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." Microsoft, 253 F.3d at 58. "As a general rule, any firm, even a monopolist, may . . . bring its products to market whenever and however it chooses." Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 925 n.7 (3d Cir. 1999) (quoting Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 (2d Cir. 1979)).

Mylan offers no evidence of anticompetitive conduct. Defendants did not exclude competition when they reformulated Doryx, introduced new versions of Doryx into the marketplace, marketed the new versions of Doryx, and withdrew old versions. The undisputed evidence shows that Mylan competes with Defendants and that Defendants have not excluded Mylan from competition on the merits. Doryx capsules have been available without patent

protection since 1985, and in 2006, Sandoz introduced a generic Doryx capsule. (W.C. Ex. 382.) Although Mylan had been developing its own generic Doryx capsule since 2003, it chose to abandon that effort in January 2006. (W.C. Resp. to Mylan S.J. at 19-21.) After Defendants introduced the Doryx tablet in September 2005, Mylan began generic development and—after addressing problems raised in several FDA deficiency notices—launched its own generic 75 and 100 mg Doryx tablets in December 2010 and benefitted from 180 days of exclusivity for the tablets. (W.C. Ex. 377); see F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013) (noting value of 180 day exclusivity period and that "vast majority" of generic profits materialize during exclusivity period). In 2011, Mylan became the sole producer of 75 and 100 mg Doryx after Defendants stopped selling those dosages. (W.C. Resp. to Mylan S.J. at 23.) Remarkably, during this time, Mylan raised the price of its generic 75 and 100 mg Doryx to a higher price than the last reported price of branded Doryx. (Id.) After Defendants introduced the 150 mg tablet, Mylan was able to develop and sell its own 150 mg generic tablet at a gross profit of $146 million over three years. (W.C. S.J. at App. 7.)

Throughout this period, doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug. As I have described, undisputed evidence shows that managed care organizations promoted the substitution of lower-cost generics for branded Doryx even though they are not AB-rated. (W.C. Ex. 64.) When the price of Doryx increased, patients, pharmacists, and physicians switched to other drugs. (See, e.g., W.C. Ex. 53 at 43.)

Insofar as branded Doryx maintained market share, the record confirms that this was a function of Defendants' considerable efforts to promote Doryx. Since 2007, Warner Chilcott's

promotional expenditures have increased each year, averaging approximately 10% of its net revenue from the sale of Doryx. (W.C. Ex. 53, Addanki Rep. at 30.) These efforts include advertising and promoting sales through contact with health care professionals. In 2011, these costs were approximately $23 million. (Id., Att. 3.). In 2012 (the latest year for which figures were provided), these costs were approximately $22 million. (Id.)

It is undisputed that Mylan expended no funds to promote its generic versions of Doryx. Mylan explains that "[n]o rational company would have undertaken [promotional expenses]" because

> the cost associated with detailing physicians and other extraordinary marketing tactics would essentially eliminate the cost savings associated with generic entry and any marketing of a generic would likely redound to the benefit of manufacturers.

(Mylan S.J. at 51.) Mylan thus seeks to transform its own refusal to incur promotion costs into Defendants' anticompetitive conduct. As I have described, however, Mylan's generic 150 mg Doryx tablet generated a gross profit of $146 million over three years—without Mylan spending a cent on "extraordinary tactics," such as promoting its product to doctors and the public. (W.C. S.J. at App. 7.) In 2010, Mylan took full advantage of the 180 days of exclusivity provided by statute, and, after Defendants stopped making 75 and 100 mg Doryx tablets, Mylan significantly raised the price of generic Doryx. 21 U.S.C. § 355; (W.C. Ex. 377; W.C. Resp. to Mylan S.J. at 23). Spending some of its revenue on advertising would have lessened Mylan's now-increased profits. Mylan chose not to do so, relying instead on the "promotion" provided by state automatic substitution laws. Mylan is thus a "victim" of its own business strategy, not Defendants' "predatory" conduct.

The gravamen of Mylan's complaint is that Defendants' "anticompetitive product changes" were exclusionary because Mylan's generic would not automatically be substituted

unless Mylan redesigned the generic to match the new version of Doryx and secured an AB-rating from the FDA. (Mylan S.J. at 39.) The Third Circuit has never ruled that this kind of conduct is anticompetitive. It has repeatedly held that "[c]onduct that merely harms competitors . . . while not harming the competitive process itself is not anticompetitive." Broadcom 501 F.3d at 308; accord Dentsply Int'l, Inc., 399 F.3d at 187 ("There must be proof that competition, not merely competitors, has been harmed."). Moreover, where the Third Circuit has found exclusionary conduct, the excluded party is invariably smaller than the excluder. See, e.g., Dentsply Int'l, Inc., 399 F.3d at 191 ("Consumer injury results from the delay that the dominant firm imposes on the smaller rival's growth." (quoting Herbert Hovenkamp, Antitrust Law ¶ 1802c, at 64 (2d ed. 2002))). As I have described, Mylan is considerably larger than either Defendant.

To establish anticompetitive conduct, "it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." Dentsply Int'l, Inc., 399 F.3d at 191. Even if Defendants' product changes prevented Mylan from taking advantage of more profitable means of distributing its generic Doryx, the changes did not "bar" Mylan from the market or "severely restrict the market's ambit." Id.

The Third Circuit's rulings respecting exclusionary conduct are instructive. In Dentsply, the alleged monopolist manufactured and controlled over 90% of the market for prefabricated artificial teeth, which it sold to dental labs through dealers—middlemen who were the labs' "preferred source" of artificial teeth. 399 F.3d at 192. Dentsply required exclusive contracts with its dealers: if they sold other manufacturers' artificial teeth, they could not sell Dentsply products. Id. at 185. The Third Circuit concluded that these contracts were exclusionary

because they prevented competitors from accessing the only practicable means of reaching customers. Id. at 193 (noting that dealers had "controlling degree of access" to the customers). In LePage's Inc., the Third Circuit ruled that 3M's "bundled rebates" across its product lines were akin to "tying" contracts that had the practical effect of completely excluding LePage's products from the market. LePage's Inc. v. 3M, 324 F.3d 141, 157 (3d Cir. 2003) (en banc). In Broadcom Corp., Qualcomm falsely committed to license its proprietary mobile wireless technology on "fair, reasonable, and non-discriminatory" terms—thus "locking in" the market. It then refused to license the proprietary technology to competitors on the promised terms. Broadcom Corp., 501 F.3d at 314. The Third Circuit ruled that because the practical effect of Qualcomm's deceptive conduct was to exclude competition, it was anticompetitive. Id.

Here, there was no exclusionary conduct. Mylan remains able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development. Mylan instead seeks to take advantage of generic substitution laws and thus increase its profits. Defendants have no duty to facilitate Mylan's business plan by keeping older versions of branded Doryx on the market. See Verizon Commc'ns Inc., 540 U.S. at 415 (no general duty to aid competitors). Defendants certainly did not exclude competition by denying Mylan the opportunity to take advantage of a regulatory "bonus."

Mylan relies on decisions addressing the anticompetitive effects of changes to complementary products in separate markets. See Microsoft, 253 F.3d at 87 (Microsoft eliminated consumer choice by bundling together its Windows operating system and its Internet Explorer web browser); C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1382 (Fed. Cir. 1998) (sustaining jury verdict where Bard modified its biopsy gun to render it incompatible with its competitors' replacement needles and thus excluded competition in the complementary

market for replacement needles); but see Berkey Photo, Inc., 603 F.2d at 279 (rejecting antitrust liability when Kodak introduced a new camera that was incompatible with existing film). These decisions are inapposite because Mylan does not produce a complementary product or compete with Defendants in a complementary market. As I have explained, Mylan and Defendants vigorously compete in a single market for oral tetracyclines

Mylan also cites to a handful of procedurally inapposite decisions respecting whether product hopping in the pharmaceutical industry is a Section 2 violation. See New York v. Actavis, PLC, No. 14-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014) (entering preliminary injunction that prevents a branded drug manufacturer from withdrawing an older version of its Alzheimers drug from the market); In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., No. 13-2445, 2014 WL 6792663, at *10 (E.D. Pa. Dec. 3, 2014) (denying branded drug manufacturer's motion to dismiss); Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (granting branded drug manufacturer's motion to dismiss); Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 422 (D. Del. 2006) (denying branded drug manufacturer's motion to dismiss). These courts addressed whether the introduction of a new product combined with other, exclusionary conduct can state a claim for relief under the Sherman Act. See, e.g., In re Suboxone, 2014 WL 6792663, at *10 ("The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit."). These decisions thus establish, at most, that a generic manufacturer can plead a plausible antitrust violation when a branded drug manufacturer redesigns the branded drug.

I, too, denied Defendants' motions to dismiss Mylan's Complaint. Mylan Pharm., Inc. v. Warner Chilcott Pub. Co., No. 12-3824, 2013 WL 5692880, at *2 (E.D. Pa. June 12, 2013). Given the absence of controlling authority (and *any* appellate authority), I thought it prudent to consider the legality of product hopping with the benefit of a fully developed record. That record now underscores that Defendants have not violated Section 2.

Adoption of Mylan's theory of "anticompetitive product redesign" could well have adverse, unintended consequences. *Any* time a pharmaceutical manufacturer changes the formulation of a branded drug and so compels a manufacturer to reformulate (or, as in the instant case, formulate for the first time) its generic, this could trigger a Microsoft burden-shifting contest. Microsoft Corp., 253 F.3d at 58; In re Suboxone, 2014 WL 6792663 at *7. Once the branded drug manufacturer offered a procompetitive justification for the product change that the generic manufacturer could not rebut, courts and juries would have to determine which product changes were "sufficiently innovative" to justify their anticompetitive effects. Microsoft Corp., 253 F.3d at 58-59. Mylan has failed to offer an intelligible test of innovation "sufficiency," and I doubt that courts could ever fashion one. See Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 1000 (9th Cir. 2010) ("To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the "right" amount of innovation, which would maximize social gains and minimize competitive injury."); United States v. Microsoft Corp., 147 F.3d 935, 948 (D.C. Cir. 1998) ("Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law."); Berkey Photo, Inc.,

603 F.2d at 287 ("[N]o one can determine with any reasonable assurance whether one product is 'superior' . . . .").

Mylan's theory also risks slowing or even stopping pharmaceutical innovation. The prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs. Cf. Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 73 (3d Cir. 2010) ("The entry of summary judgment in favor of an antitrust defendant may actually be required in order to prevent lengthy and drawn-out litigation, which may have a chilling effect on competitive market forces.").

With Hatch-Waxman, Congress sought to encourage innovation and provide generic drug manufacturers a quick, less costly pathway to FDA approval. Indeed, Congress sought to "compensate" research drug companies and promote continued research amidst increased generic competition. (W.C. S.J. at 20 (citing statement of a Hatch-Waxman sponsor).) Yet, the Act is silent on product hopping. (Id. at 17.) Congress certainly could have created barriers to brand-name drug changes that could delay generic entry, but, perhaps understanding the adverse effects this could have on innovation, it did not. Courts should not seek to substitute their "legislative judgment" for that of Congress. See Tri-Bio Labs. Inc. v. United States, 836 F.2d 135, 139 (3d Cir. 1987) (Hatch-Waxman reflects a "statutory compromise of . . . competing concerns"); Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005) ("Because the balance struck between these competing goals is a quintessentially a matter for legislative judgment, the court must attend closely to the terms in which the Congress expressed that judgment.").

Finally, because I have decided that Defendants' product changes are not anticompetitive, I need not address Defendants' remaining arguments: that Mylan lacks antitrust standing, that

Mylan's claims are time-barred, and that because Defendants petitioned the FDA to make the Doryx changes, they are covered by Noerr antitrust immunity. (W.C. S.J. at 9, 39-50, 50-53.)

*B. Attempted Monopolization Claim*

To demonstrate attempted monopolization, Mylan must show (1) that Defendants engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power. Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993). Mylan's claim of attempted monopolization necessarily fails. Because Defendants' conduct was not anticompetitive, it could not constitute attempted monopolization. California Computer Products, Inc. v. Int'l Bus. Machines Corp., 613 F.2d 727, 738 (9th Cir. 1979) ("[C]onduct lawful for a monopolist must, a fortiori, be excluded as a basis for the attempt offense.").

## II. Section 1 Claim

Mylan also challenges Defendants' exclusive licensing agreement as a restraint of trade in violation of Section 1 of the Sherman Act. (Compl. ¶ 88.) The Third Circuit has held that:

> [t]o establish a violation of Section 1, a plaintiff must prove: (1) concerted action by the defendants; (2) that produced anticompetitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that it was injured as a proximate result of the concerted action.

Gordon v. Lewistown Hosp., 423 F.3d 184, 207 (3d Cir. 2005) (citations omitted). Because I have concluded that Defendants' development and introduction of the Doryx tablet were not anticompetitive, Mylan has not established the second prong of the Gordon test. Accordingly, I need not reach Defendants' argument that they are together a single economic entity incapable of antitrust conspiracy. (Mayne S.J. at 23-32.)

## III. Tortious Interference Claim

Under Pennsylvania law, to prevail on a claim for tortious interference with prospective contractual relationships, Mylan must prove:

> (1) the existence of a contractual or prospective contractual or economic relationship between the plaintiff and a third party; (2) purposeful action by the defendant, specifically intended to harm an existing relationship or intended to prevent a prospective relation from occurring; (3) the absence of privilege or justification on the part of the defendant; (4) legal damage to the plaintiff as a result of the defendant's conduct; and (5) for prospective contracts, a reasonable likelihood that the relationship would have occurred but for the defendant's interference.

Acumed LLC v. Advanced Surgical Servs., Inc., 561 F.3d 199, 212 (3d Cir. 2009). Plaintiff's claim fails on third element: Defendants' conduct was privileged. Id. at 215 (Pennsylvania law recognizes "that competitors, in certain circumstances, are privileged in the course of competition to interfere with others' prospective contractual relationships"). The privilege applies when: (1) the relation concerns a matter involved in the competition between the actor and the other; (2) the actor does not employ wrongful means; (3) his action does not create or continue an unlawful restraint of trade; and (4) his purpose is at least in part to advance his interest in competing with the other. Id.; Restatement (Second) of Torts § 768 (1979).

These criteria underscore the privileged nature of Defendants' product changes. The relation between Defendants and their customers—whether direct or indirect purchasers—concerns a matter of competition among pharmaceutical companies such as Mylan, Warner Chilcott, and Mayne. Moreover, Defendants did not employ wrongful means: I have concluded that Defendants' product development was not anticompetitive. For the same reasons, I find that the changes to Doryx were not wrongful and were not an unlawful restraint on trade. Finally, Defendants' actions were meant, at least in part, to advance their interest in competing with Mylan. In these circumstances, Mylan's tortious interference claim is not viable.

## CONCLUSION

Although Mylan had numerous opportunities to market generic Doryx, it waited until the sales of branded Doryx were so great that huge generic sales—buoyed by regulatory compulsion—were assured. Defendants' efforts to deny Mylan this regulatory windfall were hardly predatory. On the contrary, these efforts have compelled pharmaceutical giant Mylan to compete against much smaller Warner Chilcott and Mayne on the merits and price of its products. Mylan's reading of the Sherman Act would not only require federal courts to serve as FDA adjuncts, it would strongly discourage pharmaceutical development and innovation. Finally, giving generics a regulatory "preferred place" would not necessarily reduce drug prices. Once Mylan was the exclusive seller of generic 75 and 100 mg Doryx tablets, it raised prices so that they were higher than those of branded Doryx. Presumably, it would seek to do the same once its generic sales were assured by automatic substitution laws. I cannot allow Mylan, solely for its own benefit, to thus stand the Sherman Act on its head.

Accordingly, I will enter summary judgment in Defendants' favor.

An appropriate Order follows.

*/s/ Paul S. Diamond*

April 16, 2015 Paul S. Diamond, J.